

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 12, 15, 18, 21, 23, and 25-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Mazel et al. (US Pub No. 2005/0171537).

Mazel et al. disclose a device (FIG. 1) for treating spinal deformities, comprising a spinal anchoring element (bottom part, ref. #6) adapted to seat first and second spinal fixation elements (ref. #4,5) and at a distance spaced apart from one another, the spinal anchoring element having a bore (ref. #15) extending therethrough; a fastening element (ref. #3) adapted to extend through the bore to mate the spinal anchoring element to bone; and a closure mechanism (ref. #7) mated to the spinal anchoring element to lock each of the first and second spinal fixation elements in a fixed position relative to the spinal anchoring element, the closure mechanism adapted to receive a locking mechanism (ref. #28) that directly engages the bore. The spinal anchoring element includes a first recess (ref. #8) adapted to receive a first spinal fixation element, and a second recess (ref. #9) spaced a distance apart from the first recess and adapted to

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receive a second spinal fixation element. The spinal anchoring element includes a central portion positioned between the first and second recesses and adapted to receive the fastening element for mating the anchoring element to bone. The central portion includes the bore extending therethrough. The closure mechanism includes a central portion (ref. #25) adapted to receive a locking mechanism for mating the closure mechanism to the spinal anchoring element. The device further comprises a locking mechanism (ref. #28) for mating the closure mechanism to the spinal anchoring element. The fastening element comprises a bone screw, and the locking mechanism comprises a set screw. The first recess is formed in a first end portion of the spinal anchoring element and the second recess is formed in a second, opposed end portion of the spinal anchoring element. Each end portion includes a superior surface and an inferior surface, the first and second recesses being formed in the superior surface. The closure mechanism includes a first end portion (ref. #10) adapted to lock a spinal fixation element within the first recess, and a second end portion (ref. #11) adapted to lock a spinal fixation element within the second recess. The device further comprising first and second spinal fixation elements (ref. #4,5) adapted to be disposed between the spinal anchoring element and the closure mechanism. Each recess has a substantially concave shape.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-17 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazel et al. (US Pub No. 2005/0171537) in view of Paul et al. (US 2004/0236327).

Mazel et al. disclose the claimed invention except for each spinal fixation element being flexible and being formed from a bioabsorbable material.

Paul et al. disclose spinal fixation element being flexible and being formed from a bioabsorbable material (paragraph [0097]) to provide an improved spinal fixation element.

It would have been obvious at the time the invention was made to construct the fixation elements of Mazel et al. being flexible and bioabsorbable in view of Paul et al. to provide a spinal improved fixation element.

Claims 10-11 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazel et al. (US Pub No. 2005/0171537) in view of Shih et al. (US 6,136,002).

Mazel et al. disclose the claimed invention except for bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions.

Shih et al. disclose bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions for gripping bone.

It would have been obvious at the time the invention was made to construct the fixation elements of Mazel et al. with bone engaging members (spikes) extending

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distally from the inferior surface of each of the first and second end portions in view of Shih et al. to grip bone.

Claims 1-9, 12, 15, 18, 21, 23, and 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Assaker et al. (US 7,008,426). Also, see evidentiary reference to Shih et al. (U.S. Patent No. 6,136,002).

Assaker et al. disclose a device (FIG. 9) for treating spinal deformities, comprising a spinal anchoring element (bottom part of ref. #6) adapted to seat first and second spinal fixation elements (ref. #2 3) and at a distance spaced apart from one another, the spinal anchoring element having a bore (ref. #30) extending therethrough; a fastening element (ref. #8) adapted to extend through the bore to mate the spinal anchoring element to bone; and a closure mechanism (top part of ref. #6) mated to the spinal anchoring element to lock each of the first and second spinal fixation elements in a fixed position relative to the spinal anchoring element, the closure mechanism adapted to receive a locking mechanism (ref. #10) that directly engages the bore. The spinal anchoring element includes a first recess (ref. #13) adapted to receive a first spinal fixation element, and a second recess (ref. #52) spaced a distance apart from the first recess and adapted to receive a second spinal fixation element. The spinal anchoring element includes a central portion positioned between the first and second recesses and adapted to receive the fastening element for mating the anchoring element to bone. The central portion includes the bore extending therethrough. The closure mechanism includes a central portion adapted to receive a locking mechanism for mating the closure mechanism to the spinal anchoring element. The device further

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comprises a locking mechanism for mating the closure mechanism to the spinal anchoring element. The fastening element comprises a bone screw, and the locking mechanism comprises a set screw. The first recess is formed in a first end portion of the spinal anchoring element and the second recess is formed in a second, opposed end portion of the spinal anchoring element. Each end portion includes a superior surface and an inferior surface, the first and second recesses being formed in the superior surface. The closure mechanism includes a first end portion adapted to lock a spinal fixation element within the first recess, and a second end portion adapted to lock a spinal fixation element within the second recess. The device further comprising first and second spinal fixation elements adapted to be disposed between the spinal anchoring element and the closure mechanism. Each recess has a substantially concave shape.

Assaker et al. disclose the claimed invention except for the closure mechanism being removably mated to the spinal anchoring element (*i.e.* Assaker et al. disclose an integral closure mechanism/spinal anchoring element instead of two separate pieces).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Assaker et al. with the closure mechanism being removably mated to the spinal anchoring element (*i.e.* the closure mechanism being non-integral with the spinal anchoring element), since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. In this case, having a separate closure mechanism could provide benefits, such as making removal of the rod ref. #2 easier during surgical revision, and also making it easier to replace closure

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mechanism ref. #6 if the closure mechanism was accidentally damaged during insertion of the rod without having to replace the entire piece (closure mechanism and spinal anchoring element). Also, see evidentiary reference to Shih et al. (U.S. Patent No. 6,136,002), which shows that clamps meant for holding rods can be constructed as two separate pieces, closure mechanism (ref. #14) and spinal anchoring element (ref. #12).

Claims 16-17 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Assaker et al. (US 7,008,426) in view of Paul et al. (US 2004/0236327).

Assaker et al. disclose the claimed invention except for each spinal fixation element being flexible and being formed from a bioabsorbable material.

Paul et al. disclose spinal fixation element being flexible and being formed from a bioabsorbable material (paragraph [0097]) to provide an improved spinal fixation element.

It would have been obvious at the time the invention was made to construct the fixation elements of Assaker et al. being flexible and bioabsorbable in view of Paul et al. to provide a spinal improved fixation element.

Claims 10-11 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Assaker et al. (US 7,008,426) in view of Shih et al. (US 6,136,002).

Assaker et al. disclose the claimed invention except for bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions.

Shih et al. disclose bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions for gripping bone.

It would have been obvious at the time the invention was made to construct the fixation elements of Assaker et al. with bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions in view of Shih et al. to grip bone.

Claims 1-6, 8-12, 15, 18, 21, 23, 25-26, 28-31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gertzbein et al. (U.S. Patent No. 5,620,443). Also, see evidentiary reference to Shih et al. (U.S. Patent No. 6,136,002).

Gertzbein et al. disclose a device (FIG. 1) for treating spinal deformities, comprising a spinal anchoring element (bottom part, ref. #20) adapted to seat first and second spinal fixation elements (ref. #11) and at a distance spaced apart from one another, the spinal anchoring element having a bore (ref. #16) extending therethrough; a fastening element (ref. #30) adapted to extend through the bore to mate the spinal anchoring element to bone; and a closure mechanism (top part, ref. #23) mated to the spinal anchoring element to lock each of the first and second spinal fixation elements in a fixed position relative to the spinal anchoring element, the closure mechanism adapted to receive a locking mechanism (ref. #40) that directly engages the bore. The spinal anchoring element includes a first recess (see FIG. 2, right) adapted to receive a first spinal fixation element, and a second recess (see FIG. 2, left) spaced a distance apart from the first recess and adapted to receive a second spinal fixation element. The spinal anchoring element includes a central portion (see FIG. 2, central portion, and

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also FIG. 5) positioned between the first and second recesses and adapted to receive the fastening element for mating the anchoring element to bone. The central portion includes the bore extending therethrough. The closure mechanism includes a central portion (at ref. #16, 41) adapted to receive a locking mechanism for mating the closure mechanism to the spinal anchoring element. The device further comprises a locking mechanism (ref. #40) for mating the closure mechanism to the spinal anchoring element. The fastening element comprises a bone screw. The first recess is formed in a first end portion of the spinal anchoring element and the second recess is formed in a second, opposed end portion of the spinal anchoring element. Each end portion includes a superior surface and an inferior surface, the first and second recesses being formed in the superior surface. The closure mechanism includes a first end portion adapted to lock a spinal fixation element within the first recess, and a second end portion adapted to lock a spinal fixation element within the second recess. The device further comprising first and second spinal fixation elements (ref. #11) adapted to be disposed between the spinal anchoring element and the closure mechanism. Each recess has a substantially concave shape. The device has bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions

Gertzbein et al. disclose the claimed invention except for the closure mechanism being removably mated to the spinal anchoring element (*i.e.* Gertzbein et al. disclose an integral closure mechanism/spinal anchoring element instead of two separate pieces).

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Gertzbein et al. with the closure mechanism being removably mated to the spinal anchoring element (*i.e.* the closure mechanism being non-integral with the spinal anchoring element), since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. In this case, having a separate closure mechanism could provide benefits, such as making removal of the rod ref. #2 easier during surgical revision, and also making it easier to replace closure mechanism ref. #6 if the closure mechanism was accidentally damaged during insertion of the rod without having to replace the entire piece (closure mechanism and spinal anchoring element). Also, see evidentiary reference to Shih et al. (U.S. Patent No. 6,136,002), which shows that clamps meant for holding rods can be constructed as two separate pieces, closure mechanism (ref. #14) and spinal anchoring element (ref. #12).

Claims 16-17 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gertzbein et al. (U.S. Patent No. 5,620,443) in view of Paul et al. (US 2004/0236327).

Gertzbein et al. disclose the claimed invention except for each spinal fixation element being flexible and being formed from a bioabsorbable material.

Paul et al. disclose spinal fixation element being flexible and being formed from a bioabsorbable material (paragraph [0097]) to provide an improved spinal fixation element.

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It would have been obvious at the time the invention was made to construct the fixation elements of Gertzbein et al. being flexible and bioabsorbable in view of Paul et al. to provide a spinal improved fixation element.

Claims 7 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gertzbein et al. (U.S. Patent No. 5,620,443) in view of Assaker et al. (U.S. Patent No. 7,008,423).

Gertzbein et al. disclose the claimed invention except the locking mechanism being a setscrew (rather, Gertzbein et al. disclose a tightening nut).

Assaker et al. discloses using a setscrew to tighten a clamp by interaction with threads on a bone screw used to attach the clamp to the body.

It would have been obvious at the time the invention was made to substitute the tightening nut mechanism of Gertzbein et al. with the setscrew tightening mechanism of Assaker et al., since such is a functional equivalent and would have provided the same predictable result of tightening the clamp by interaction with threads on a bone screw used to attach the clamp to the body.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

The rejections are deemed proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MARY HOFFMAN** whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733
/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733